

PRESS RELEASE No 174/22

Luxembourg, 27 October 2022

The Opinion of the Advocate General in Case C-688/21 | Confédération paysanne and Others (*in vitro* random mutagenesis)

Genetically modified plant varieties: according to the First Advocate General Szpunar, random mutagenesis applied *in vitro* must be excluded from the scope of EU law concerning deliberate release into the environment of GMOs

Such an exclusion would not exempt the plant varieties obtained by those techniques from all control

This case follows on from the case *Confédération paysanne and Others*,¹ in which the Court of Justice was asked to rule on the interpretation of Directive 2001/18.² The Court ruled that mutagenesis methods or techniques which have emerged or have been developed since the adoption of that legislation must not be excluded from the scope of that directive.

Ruling on the dispute between the Confédération paysanne (a French agricultural syndicate) as well as seven associations opposed to genetically modified organisms (GMO), against the Premier ministre (Prime Minister) and the ministre de l'Agriculture et de l'Alimentation (Ministry of Agriculture and Food) on the exclusion of certain mutagenesis techniques from the scope of French national legislation governing the cultivation, marketing and use of GMO, the Conseil d'État (France) has asked the Court to interpret Directive 2001/18 in the light of the *Confédération paysanne and Others* judgment concerning the technique or method of genetic modification known as random mutagenesis applied *in vitro*.

In today's Opinion, First Advocate General Maciej Szpunar observes that the judgment in *Confédération paysanne and Others* relates, in essence, to the exclusion of random mutagenesis applied *in vitro* and of directed mutagenesis from the scope of Directive 2001/18. However, the Court did not expressly rule on the method of random mutagenesis applied *in vitro*, which is the subject of the proceedings in this case. The First Advocate General also states that the solution to the dispute depends on the answer to the question as to the possible exclusion of the method of random mutagenesis applied *in vitro* from the scope of Directive 2001/18.

As regards the two criteria drawn from the case-law *Confédération paysanne and Others* relating to the exclusion of certain techniques or methods of mutagenesis from the scope of Directive 2001/18, the First Advocate General points out that their application **when assessing the safety of mutagenesis *in vitro* may produce different results depending on the entity subject to that cultivation, thus inducing a likelihood of confusion regarding the scope of application of Directive 2001/18** and, consequently, would necessarily compromise the uniformity of the interpretation of EU law. In that regard, the First Advocate General proposes to the Court to clarify definitively whether random mutagenesis *in vitro* is excluded from the scope of Directive 2001/18.

According to the First Advocate General, the questions do not concern the differences between the plants obtained but the differences between the methods used to obtain them. The aim of Directive 2001/18, however, is not to

¹ Judgment of 25 July 2018, *Confédération paysanne and Others*, [C-528/16](#) (see Press Release No [111/18](#)).

² Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p.1).

regulate the method of genetic modification but to establish an authorisation procedure for the release into the environment of organisms obtained by means of those methods. In that regard, a technique or a method of genetic modification liable to be excluded from Directive 2001/18 therefore concerns **not mutagenesis itself but the organisms obtained by that method. The identity of those organisms therefore means that the differentiated treatment of the methods used to obtain them is unjustified.**

Furthermore, as regards the distinction between random mutagenesis applied *in vitro* and *in vivo*, the First Advocate General is of the opinion, **on the basis of the preliminary report of the European Food Safety Authority and of the opinion of the Haut Conseil des biotechnologies (High Council for Biotechnology) on the matter**, that there is **no scientific justification for that distinction and no legal justification for treating differently the organisms obtained by means of those two techniques**, as **nothing in the text of Directive 2001/18 indicates that the EU legislature wanted to differentiate mutagenesis techniques according to the material to which the mutagenesis was applied**. In addition, there is no indication that the EU legislature attached any significance to a technique excluded from the scope of Directive 2001/18 being associated with *in vitro* cultivation.

Accordingly, **the First Advocate General proposes to the Court to confirm the exclusion of random mutagenesis *in vitro* from the scope of Directive 2001/18.**

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

Unofficial document for media use, not binding on the Court of Justice.

The [full text](#) of the Opinion is published on the CURIA website on the day of delivery.

Press contact: Jacques René Zammit ☎ (+352) 4303 3355.

Pictures of the delivery of the Opinion are available from "[Europe by Satellite](#)" ☎ (+32) 2 2964106.

Stay connected!

